# Drug Information Sheet("Kusuri-no-Shiori")

Self-injection

Revised: 08/2022

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

**Brand name:ENBREL 50mg Pen 1.0mL for S.C. Injection**

**Active ingredient:**Etanercept (genetical recombination)

**Dosage form:**colorless to yellow or faint brown, limpid to opalescent pen-type injectable preparation

**Imprint or print on wrapping:**

## Effects of this medicine

This medicine suppresses action of TNF, which is considered to be a primary factor that is related to immune mechanism, inflammation and pain, improves symptoms associated with rheumatoid arthritis and prevents the damage of joints and bones.

It is usually used to treat rheumatoid arthritis with inadequate response to existing therapies (including prevention of structural joint damage). However, it does not completely cure the disease.

## The following patients may need to be careful when using this medicine.Be sure to tell your doctor and pharmacist.

・If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.

If you have infection, tuberculosis, demyelinating disorders such as multiple sclerosis or its past history, congestive heart failure, blood disorders or its past history or a history of interstitial pneumonia.

If you are a hepatitis B virus carrier or have a history of hepatitis B.

・If you are pregnant or breastfeeding.

・If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

## Dosing schedule (How to take this medicine)

・Your dosing schedule prescribed by your doctor is(( to be written by a healthcare professional))

・In general, for adults, subcutaneously inject 1 kit (50 mg of the active ingredient) at a time, once a day, once a week. Strictly follow the instructions.

・The contents of a kit should be used all at once.

・Choose a different injection site each time. (Inject at least 3 cm apart from the previous injected site.)

・Do not inject into an irritable skin site, or a site with wound, redness or induration (a site harder than around).

・Do not massage the injected site after subcutaneous injection.

・Before use, leave this medicine at room temperature for about 15 to 30 minutes. Do not remove the cap of the pen tip until this medicine reaches room temperature.

・Inspect the liquid in the kit before use. There may be small white protein particles, however you can use this medicine as usual. Do not use this medicine if there are any colored particles or the liquid has discolored. And consult with your doctor.

・You may self-inject this medicine if you or your family receive appropriate instructions in a medical institution for self-injection at home.

・Before using this medicine, the presence or absence of hepatitis B virus infection is checked in blood tests.

・If you miss a dose, use the missed dose when you notice. Thereafter, inject the next dose at the interval of once a week. However, if the next dose is scheduled on the following day, skip the dose and inject a dose at the next indicated time. You should never use two doses at one time.

・If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.

・Do not stop using this medicine unless your doctor instructs you to do so.

## Precautions while taking this medicine

・This medicine suppresses the action of substances that regulate the immune response and may make you more susceptible to infection. If any symptoms suggestive of blood disorder or infection, such as fever, persistent fever, malaise, sore throat, contusion or pallor occur, consult with your doctor immediately.

・Before using this medicine, in addition to a medical interview and chest X-ray, an interferon-gamma release test or tuberculin reaction test, and possibly a chest CT scan, should be performed to determine the presence of tuberculosis infection. In addition, patients with a history of tuberculosis will undergo periodic chest x-rays and other tests while using this medicine. If any symptoms suggestive of tuberculosis (persistent cough, fever, etc.) occur, contact your doctor immediately.

・If you have ever had hepatitis B or have been infected with hepatitis B virus in the past, periodic liver function tests and hepatitis virus marker tests will be performed. If any symptoms suggestive of reactivation of hepatitis B virus (fever, malaise, yellow discoloration of skin and white of eyes, loss of appetite, etc.) occur, contact your doctor immediately.
・Undergo the tests at the specified date and time.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include infections (bronchitis, nasopharyngitis, etc.), injection site reactions (erythema, itch, swelling, pain, etc.), headache, nausea, dermatitis, dizziness, diarrhea, rash, pruritus (itch), liver disorder (general malaise, loss of appetite, etc.), rhinitis, stomatitis, alopecia, increased cough, abdominal pain, dry mouth, gastric ulcer, peripheral edema and fever. If any of these symptoms occur, consult with your doctor or pharmacist. Do not scratch or touch the injection site.

**The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.**

・chills, fever, general malaise [sepsis, pneumonia (including pneumocystis pneumonia), opportunistic infections such as fungal infection]
・persistent slight fever, persistent cough (for 2 weeks or more), general malaise [tuberculosis]
・general redness, general edema, breathing difficulty [serious allergic reactions]
・persistent fever, sore throat, paleness of the face [serious blood disorders]
・reduced visual acuity/diplopia, numbness/pain/motor paralysis [demyelinating disorders]

**The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.**

**Storage conditions and other information**

・Keep out of reach of children. Store at 2 to 8 degrees Celsius (in the refrigerator), away from light and avoid freezing.
・Discard the remainder. Do not store them. Please consult with your pharmacy or medical institution, since proper disposal of the unused medicines requires attention. Do not give the unused medicines to others.
・Discard used injection syringes in a dedicated trash container as directed by the medical institution.
・Do not reuse used injection syringes.
・Do not receive live vaccines (such as rubella and mumps vaccines) due to the risk of infection. If you wish to receive live vaccines for prevention, be sure to inform and consult with your doctor that you are using this medicine.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.